MAIL STOP AMENDMENT
Attorney Docket No. 23057-XY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

PATIERNO et al.

Serial No. 10/052,498 Group Art Unit: 1635

Filed: January 23, 2002 Examiner: Brian Whiteman

For: **UTEROGLOBIN GENE THERAPY FOR EPITHELIAL CELL CANCER**

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Official Action dated August 20, 2004. The one month shortened statutory period for response was set to expire on September 20, 2004. A five month Petition for Extension of Time and fee are attached hereto, extending the period for reply to February 20, 2005. In view of the following remarks and amendments, Applicants respectfully request the Examiner to proceed with examination of this application, and to allow all claims pending in this application.

SUMMARY OF RESTRICTION AND ELECTION REQUIREMENTS

Inventive Groups. The Examiner has required restriction of claims 74-202 to one of the following Inventive Groups under 35 U.S.C. 121:

I. Claims 74-152, drawn to several methods for treating cancer consisting of inhibiting tumorigenesis, inhibiting tumor cell growth; interfering with invasion of a local extracellular matrix; inhibiting tumor-induced angiogenesis; inhibiting or decreasing the activity of metalloproteinases required for degradation of an extra-cellular matrix; treating prostate cancer; preventing or inhibiting metastasis of a cancer; repairing a dysfunctional gene to prevent or inhibit metastasis of a cancer; comprising in vivo gene therapy using a polynucleotide which encodes a sequence corresponding to uteroglobin in a vector, classifiable in class 514, subclass 44.

II. Claims 153-202, drawn to several methods for treating cancer consisting of: inhibiting tumorigenesis, inhibiting tumor cell growth; interfering with invasion of a local extracellular matrix; inhibiting tumor-induced angiogenesis; inhibiting or decreasing the activity of metalloproteinases required for degradation of an extra-cellular matrix; treating prostate cancer; preventing or inhibiting metastasis of a cancer; repairing a dysfunctional gene to prevent or inhibit metastasis of a cancer; comprising ex vivo gene therapy using a polynucleotide which encodes a sequence corresponding to uteroglobin in a vector, classifiable in class 424, subclass 93.21.

As the basis for this restriction requirement, the Official Action states the following:

> Invention I and Invention II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which

generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Invention I is directed to in vivo gene therapy and invention II is directed to ex vivo gene therapy. The differences between Invention I and Invention II are further underscored by their divergent classification and independent search status.

II. Species Election. The Examiner further requires an election of species to one of the following patentably distinct species of the claimed invention of Group I or Group II: wherein the other treatment is selected from the group consisting of surgical intervention, radiation therapy, hormonal therapy, immunotherapy, chemotherapy, cryotherapy, and gene therapy.

ELECTIONS

Applicants elect Group I (claims 74-152) as the Inventive Group for Examination, and surgical intervention as the species of "second therapy" with which the primary, elected *in vivo* gene therapy, is to be combined. Because all elected claims have in common an element relating to *in vivo* administration of a polynucleotide which encodes a uteroglobin, all elected claims 74-152 are readable on the elected species.

CONCLUSION

Based upon the above remarks, Applicants respectfully request the Examiner to reconsider and withdraw the restriction

requirement, and to examine all of the claims pending in this application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the telephone number and address listed below.

Respectfully submitted,

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Date: February 22, 2005 By:

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